GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3232
ANSWERED ON:06.12.2016
Drug Pricing Policy
Chautala Shri Dushyant;Jayadevan Shri C. N.;Reddy,Kotha Prabhakar

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government is considering a proposal to overhaul the drug pricing policy and ease regulatory framework to facilitate smooth business environment for pharmaceutical companies;

(b) if so, the details and objectives thereof;

(c) whether the Government has decided to dismantle the National Pharmaceutical Pricing Authority and if so, the details thereof and the reasons therefor; and

(d) whether the Government has established any other agency for issuing licences and approval of new drugs and if so, the details thereof?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): There is no proposal at present to overhaul the drug pricing policy. However, minor changes are made in the DPCO, 2013 from time to time to facilitate a smooth business environment and in the larger public interest. The licenses for manufacturing, sale and distribution of drugs under the provisions of Drugs & Cosmetics Act and Rules there under are issued by Licensing Authority appointed by State Governments. However, for new drug, the permission/ approval is required to be obtained from Central Drugs Standard Control Organization (CDSCO) under Ministry of Health & Family Welfare, before obtaining manufacturing license from the State Licensing Authority. In order to streamline the regulatory process and to improve the efficiency and transparency in CDSCO, various measures have been taken including recently introduced e-governance in the form of 'SUGAM' for online submission and permission of various applications for grant of various licenses/ approvals.
(c): No, Madam.
(d) No, Madam. Approval of new drugs is granted by Central Drugs Standard Control Organization (CDSCO) and manufacturing licenses are granted by State Licensing Authority.
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